

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 8--CERTIFICATION OF OPIOID TREATMENT PROGRAMS--Table of Contents

Subpart C--Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

Sec. 8.21 Applicability.

The procedures in this subpart apply when:

- (a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and
- (b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.
- (c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of the accreditation body under the regulations in subpart A of this part; and
- (d) The accreditation body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

Sec. 8.22 Definitions.

The following definitions apply to this subpart C.

- (a) Appellant means:
 - (1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or
 - (2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.
- (b) Respondent means SAMHSA.
- (c) Reviewing official means the person or persons designated by the Secretary who will review the suspension

or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Sec. 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

Sec. 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

Sec. 8.25 Informal review and the reviewing official's response.

(a) Request for review. Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) Acknowledgment. Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Sec. 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) Appellant's documents and brief. Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the accreditation body is incorrect (appellant's brief).

(b) Respondent's documents and brief. Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke

appellant's certification, or approval as an accreditation body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) Reply briefs. Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) Cooperative efforts. Whenever feasible, the parties should attempt to develop a joint review file.

(e) Excessive documentation. The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) Discovery. The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

Sec. 8.27 Opportunity for oral presentation.

(a) Electing oral presentation. If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) Presiding official. The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) Preliminary conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) Time and place of oral presentation. The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) Conduct of the oral presentation.

(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of proof/standard of proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) Admission of evidence. The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) Obstruction of justice or making of false statements. Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) Post-hearing procedures. At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Sec. 8.28 Expedited procedures for review of immediate suspension.

(a) Applicability. When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) Reviewing official's response. As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) Review file and briefs. Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) Oral presentation. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with Sec. 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with Sec. 8.27(c) and will conduct the oral presentation in accordance with the procedures of Secs. 8.27(e), (f), and (g).

(e) Written decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Sec. 8.33 apply.

(f) Transmission of written communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

Sec. 8.29 Ex parte communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Sec. 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) Timely review. Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) Due date. In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Sec. 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart C, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

Sec. 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Sec. 8.33 Written decision.

(a) Issuance of decision. The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) Date of decision. The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) Public notice and communications to the Drug Enforcement Administration (DEA).

(1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the Federal Register. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the Federal Register. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

Sec. 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under Sec. 8.28(e) or Sec. 8.33(a), constitutes final agency action as of the date of the decision.